

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTELLAS US LLC, ASTELLAS)	
PHARMA US, INC., and GILEAD)	
SCIENCES, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 18-1675-CFC-CJB
)	
APOTEX INC., et al.,)	(CONSOLIDATED)
)	
Defendants.)	

MEMORANDUM ORDER

Before the Court are Defendants International Medications Systems, Ltd., Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc. and Hospira, Inc.’s (collectively, the “Form G Defendants”) and Defendant Apotex Inc.’s (“Apotex,” and together with the Form G Defendants, “Defendants”) respective motions to strike portions of Plaintiffs Astellas US LLC, Astellas Pharma US, Inc. and Gilead Sciences, Inc.’s (“Plaintiffs”) supplemental infringement contentions and supplemental expert reports (the “Motions”). (D.I. 824; D.I. 830) The Court has reviewed the relevant briefing, (D.I. 825; D.I. 831; D.I. 834; D.I. 842; D.I. 847; D.I. 854; D.I. 869; D.I. 870), and it heard argument during a teleconference held on December 20, 2021. Because the parties are well-familiar with the facts regarding these disputes, and because trial is fast approaching and a prompt decision is required, the Court writes briefly here.

The first issue implicated by the Motions is whether the portions of the respective infringement contentions and expert reports are untimely. In the Court’s view, they are. The disputed content at issue relates to Plaintiffs’ theory (the “new theory”) that Defendants infringe the patents-in-suit because the respective active pharmaceutical ingredients (“API”) used in Defendants’ proposed products converts to the claimed “Form A” polymorph of regadenoson

during the manufacturing process of Defendants' finished products. (D.I. 825 at 1; D.I. 831 at 1; D.I. 842 at 1; D.I. 869 at 2; D.I. 870 at 1) There appears to be no serious dispute that Plaintiffs did not pursue this particular infringement theory during the original fact and expert discovery periods in this case. (See, e.g., D.I. 834 at 4) Instead, during the original discovery periods, Plaintiffs pressed, *inter alia*, an infringement theory (the "old theory") that Defendants infringe the patents-in-suit because the API converts to Form A *during the manufacturing process of the API, which is conducted by third-party API suppliers*. (D.I. 842 at 1; D.I. 869 at 2) Plaintiffs disclosed their new theory for the first time in October 2021. (D.I. 825 at 1 n.1; D.I. 831 at 1)

Plaintiffs' new theory is untimely, not only because it was proffered so long after the original fact discovery period (which closed in October 2020) and expert discovery period (which closed in April 2021) had ended, but also because it is premised on their expert's review of documents that were produced to Plaintiffs back in August 2020. (D.I. 869 at 2 (citing *id.*, ex. A at 143-44; *id.*, ex. B at 47)) It is thus clearly a theory that Plaintiffs could have pursued (but chose not to) prior to the close of the original fact and expert discovery periods in the case.

Plaintiffs assert that, nevertheless, any argument about untimeliness should fail because: (1) Defendants' API providers recently amended their Drug Master Files ("DMF") and Defendants recently amended their Abbreviated New Drug Applications ("ANDA"), which in turn necessitated a supplemental period of discovery in the case (which took place from May 2021 to November 2021); (2) the result of these amendment processes is that it could be more difficult for Plaintiffs to prove their old theory of infringement to be correct; and so (3) Plaintiffs should then get to generate a new, different infringement theory now. (D.I. 870 at 1) The Court disagrees. The supplemental discovery period was simply meant to allow the parties to address new, relevant facts that are related to the DMF/ANDA amendment processes (facts that, in turn,

have to do with changes made by the API providers regarding how they manufacture the APIs). (D.I. 842 at 1; *see also* D.I. 717 (Court noting that this supplemental discovery period “should not be expansive”)) To be sure, if a new fact arose during supplemental discovery that was directly related to these amendment processes, and if a party could explain how it needed to alter its contentions as a result of that new fact, then good cause would have existed to amend the contentions. But here (as noted above), Plaintiffs’ new theory is *not* premised on new facts that came about as part of the amendment processes. Instead, it is premised on old facts that were provided to Plaintiffs over a year ago. (D.I. 870 at 1 (Plaintiffs acknowledging that only after “Defendants were attempting to cure their infringement during the API supplier’s manufacturing process” did Plaintiffs’ expert decide to thus “focus[] on evidence that Form A is created by Defendants’ compounding process”)) If supplemental discovery periods like these gave parties license to introduce entirely new theories of liability into a case—theories that are unconnected to the purpose of the supplemental discovery period itself—then this would create real havoc in the scheduling and preparing-for-trial process. *Cf. TQ Delta, LLC v. Adtran, Inc.*, Civil Action No. 14-954-RGA, Civil Action No. 15-121-RGA, 2020 WL 4529865, at *1-2 (D. Del. July 31, 2020).

The second issue is whether the *Pennypack* factors¹ work to save these untimely disclosures. They do not, as nearly all of them (other than the fourth “bad faith or willfulness”

¹ In considering whether to exclude evidence relating to an untimely or otherwise improper disclosure, the United States Court of Appeals for the Third Circuit has directed district courts to weigh certain factors, known as “the *Pennypack* factors”: (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded. *See Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985); *see also Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997). Because

factor, which is not at play here) go Defendants' way. With regard to the first "surprise/prejudice" *Pennypack* factor, Defendants were understandably surprised to see Plaintiffs' new theory asserted at what is truly the 11th hour. They were prejudiced too, because they were only provided a few weeks to try to combat that theory. Had Defendants had more time, they could have investigated whether to perform additional (and lengthy) testing procedures in order to assess the accuracy of Plaintiffs' new theory, or they could have attempted to take additional discovery relevant to the theory. (D.I. 842 at 2) Yet because of the late disclosure, this was not possible. (D.I. 869 at 2 n.1 (citing *id.*, ex. A at 25-26, 33, 40-41; *id.*, ex. B at 37-39, 40-43)) As to the second and third *Pennypack* factors (the ability to cure any prejudice and the prospect for disruption of trial), here trial is set to begin in just over a month. For the reasons set out above, there is just not time to: (1) incorporate a new and significant infringement theory into the case; (2) allow Defendants to take relevant discovery; and (3) still keep the trial date. And as to the fifth "importance" *Pennypack* factor, while the new theory may be (newly) important to Plaintiffs' infringement case, it was not important enough to assert from the case's outset; nor is it the only infringement theory that Plaintiff intends to press at trial. (D.I. 842 at 2)²

For these reasons, the Motions are GRANTED and the identified portions of the respective contentions/expert reports are STRICKEN. (D.I. 824-1; D.I. 830-1)

"[t]he exclusion of critical evidence is an extreme sanction," the Third Circuit has explained that it should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks and citations omitted).

² During oral argument, it was suggested that Plaintiffs had other infringement theories beyond the two described herein. (*See also* D.I. 834 at 1 (Plaintiffs noting that they have "other theories"))

Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the document. Any such redacted version shall be submitted by no later than **December 28, 2021** for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: December 22, 2021


Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE